REMARKS

This application is subject to a restriction requirement. Applicants provisionaly elect Group I claims (1-4) for prosecution with traverse. The Examiner has merely asserted that the claimed inventions are independent and distinct without proffering any supporting argument. Prosecution should continue on the claims as filed unless the Examiner can give a reasoned argument indicating why it should not.

The drawings have received an objection for failure to show element 175 in Fig. 2B. Applicants respectfully point out that element 175 appears directly below element 100 in the drawing. A copy of the drawing as filed is included for the Examiner's review. Accordingly, this objection has been overcome.

Claim 1 has received an objection for reciting two elements shown as "c)". This objection is overcome by the amendment to the claims.

Claim 1 has been rejected under 35 USC § 112 for use of the phrase "clinically significant error". This rejection is respectfully traversed as follows.

The specification has been amended at page 17, line 5. The process of determining the probability of occurrence of a clinically significant error is described at page 16, lines 13-30. Thus, the further amplification of this process by amending the specification at page 17 does not introduce new matter.

As the specification makes plain, the invention includes a method of reducing errors in analyzers without unduly preventing the reporting of results. An indication that an error has occurred when, in fact it has not, is guarded against in this process. The probability of error thus accounts for the probability that an error has or will occur *as well as* the probability that an error

has not or will not occur. Accounting for both phenomena in probabilistic terms results in determining the probability of the occurrence of a clinically significant error. Accordingly, the invention is particularly pointed out and distinctly claimed in accordance with section 112 of the patent statutes.

The claims have also been rejected pursuant to 35 USC § 112 for the recitation of a "low" probability of a false detection of an error failure. This basis of rejection is traversed as follows.

The use of the term "low" is explained at page 17 line 15. There it explains that where one is selecting among possible failure detection schemes, that as between schemes that have different false positive probabilities, one employing the inventive method would select the scheme having the lower of the two such probabilities. Accordingly, the claimed invention is not indefinite for use of the term "low".

Similarly, the claims are not indefinite for use of the term "acceptable limit". An acceptable limit is one that comports with the ordinary use of the system to which the inventive method applies. The specification describes the source of minimal levels of acceptability at page 4, lines 14-21. There it explains that the FDA and customary tools in the industry are used to set such limits. Further, page 17, lines 1-6 describes acceptable limits in this context. More importantly, it is clear from the context of the invention as a whole that the claimed invention is directed to a method of detecting failures that is established by one who has determined what an acceptable limit is under the conditions in which the method is used. That is, it is a predetermined limit. The method is then arrived at through the selection and implementation of steps for detecting failures to that predetermined level. The selection is based on systematic quantitative (probabilistic) relationships. There is nothing indefinite about this.

The claims have also been rejected as anticipated by US Patent 5,710,723 ('723). This rejection is respectfully traversed for the following reasons.

Applicants point out that the claims have been amended to more clearly indicate that in the inventive method, failure of an analyzer attributable to multiple possible failure modes is detected by measures selected from among multiple measures for each possible failure mode. Support for this amendment is found at page 7, line 22 of the application. Practice of the invention as claimed allows one to improve the chances of detecting a failure by the product of the probabilities of detecting a failure attributable to individual modes. Page 7, line 25. Concomitantly, the choice of detection failure mode monitoring is made so that false indications of a failure are kept to an acceptable low level.

The '723 patent is directed to operation of industrial equipment, not analytical/clinical instrumentation. Thus, there is no impetus to make a failure detection system that accounts for distinguishing between high sensitivity and acceptable false positive rates as there is in the instant case. Page 3, line 25 of the instant application. In a continuous system designed for industrial use such as that of the '723 patent one expects to employ a system that erred on the side of reporting every conceivable maintenance problem. Indeed, this is seen in the background of the patent in which prior art systems are faulted for not being "foolproof". Col. 1, line 49. The '723 patent makes no mention of selection of detection measures that are based on the heightened probability of error detection one attains from the multiplicative probabilistic effect of multiple measures for detecting each failure mode while reducing the probability of a false positive error detection. Thus, the '723 patent does not anticipate the instant invention. Since nothing in the '723 patent suggests such an approach either, it does not render the instant invention obvious. This rejection is overcome.

The claims have also been rejected as anticipated by US Patent 5,315,529 ('529). This rejection is respectfully traversed for the following reasons.

The '529 patent is directed entirely to external monitoring of fluid vessels such as by the placement of sensors in the environment around the vessel. Col. 1, line 42; Col 3, line 1. The methods, systems, and devices described in the patent are all directed to detecting one type of event in a fluid containment vessel—a leak. Errors that can result from assay failures that are not leaks (e.g., dilution errors) cannot be determined because there are no events that are detected other than leaks. Indeed, the '529 patent is not directed to assay failures at all, let alone assays for which failures can be detected.

The steps of "selecting and implementing multiple error detection measures for each failure mode based on their probability of reducing errors to an acceptable limit along with a low probability of the false detection of an assay failure" does not occur in and is not suggested by the '529 patent. Instead, the patent notes that "In general, the greater number of sensors 30 utilized increases the speed with which leaks 60 may be detected and also increases confidence that a leak 60 will not be missed by the sensors" Col. 5, line 22. This is a "more is better" approach commonly seen in the prior art. It is inapposite with the approach taken in the instant application. Here, failure detection measures take advantage of the statistical relevance of the pathway in which the failure modes occur. This allows one to increase the probability of detecting a failure without necessarily relying on an abundance of sensors, the proliferation of which results in increased false reports of errors. *C.f.,* Page 5, line 12 of the instant application. Since, among other things, the '529 patent does not contain the claim elements described above, it cannot anticipate the instant application.

The instant invention is not rendered obvious by the '529 patent either. As noted above, the patent is from an entirely different field from that of the instant invention. One skilled in the

art would not look to it for guidance in designing failure detection schemes for clinical analyzers. Assuming arguendo, however, that they would, the patent would be read to suggest placing many fluid sensors on the floor over which the analyzer is placed. *See*, col. 2, line 47.

There is nothing in the reference to suggest the design and placement of failure detection measures based on a multiplicitive amplification of the probability of detecting and reporting the cause of each failure mode as in the instant application. In the cited reference a statistical test is applied to the activation of an alarm to help determine whether a sensor reading is indicative of a real or false event. These two approaches are wholly different. In the first, one uses statistical tools to determine where and how to place detection measures while in the latter one uses statistical tools to determine whether the event that is detected is real or not. Thus, the '529 patent neither anticipates nor renders obvious the instant invention and this rejection is overcome.

Based on the foregoing, applicants believe the application is now in condition for allowance. Favorable reconsideration and notice of allowance are solicited. If any questions arise which can be disposed through interview, the Examiner is encouraged to contact Applicants' attorney at the telephone number listed below.

Please charge any fees which may be required for this submission to Johnson & Johnson Deposit Account No. 10-0750/CDS-215/TFV.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

1. A method for detecting failures that can result from multiple failure modes in an analyzer for conducting clinical assays comprising:

a) identifying potential errors that can result in assay failures in an analyzer

b) identifying potential sources of the potential errors identified in a),

c) determining the probability that an error source so identified will result in a clinically significant error,

d) identifying potential error detection measures corresponding to the source of potential errors,

e) e selecting and implementing ~~such~~ multiple error detection measures for each failure mode based on their probability of reducing errors to an acceptable limit along with a low probability of the false detection of an assay failure.